UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC.,

Defendants.

Case No. 2:21-cv-10312

Hon. Stephen J. Murphy, III

PLAINTIFF'S INITIAL BRIEF ON CLAIM CONSTRUCTION ISSUES FOR MARKMAN HEARING

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STATEMENT OF THE CASE

Plaintiff, Trutek Corp. ("Trutek") is the owner of U.S. Patent No. 8,163,802 B2 ("the '802 Patent") for "Electrostatically Charged Multi-Acting Nasal Application, Product, and Method." The '802 Patent issued on April 24, 2012 to Ashok Wahi who assigned the patent to Trutek. The '802 Patent has 23 claims. Claims 1, 2, and 8 are independent claims. Claims 3-7 depend from claim 2, and claims 9-23 depend from claim 8. Claim 1 recites a method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation. Claims 2 and 8 recite formulations for electrostatically inhibiting harmful particulate matter from infecting and individual through nasal inhalation. At issue in this case are claims 1, 2, 6, and 7. A claim chart explaining the claim limitations for each asserted claim element is attached hereto as Exhibit A. A copy of the '802 Patent is attached hereto as Exhibit B.

The '802 Patent issued from U.S. Patent Application No. 12/467,271 filed on May 16, 2009. The Application was published by the United States Patent and Trademark Office ("USPTO") as Application Publication No. 2010/0004337 A1.

The '802 Patent discloses a method and formulations. Those formulations are applied into and around a person's nasal passages. Once

applied, the formulations create an electrostatically charged thin film. Oppositely charged airborne particles (including microorganisms) in the vicinity of the skin or tissue of the nasal passages are attracted to the thin film. The thin film traps and holds them. The formulations contain a biocidic agent that renders the trapped microorganisms harmless. Several formulations are disclosed.

Claim 1 recites a method wherein a formulation is applied to a person's nasal passages forming a thin film, which adheres to the skin or tissue of his nasal passages. The applied formulation creates an electrostatically charged field in and around the nasal passages, thereby attracting airborne particles including those that are harmful. The electrostatically charged thin film holds these particles in place. The formulation contains at least one ingredient that renders the particles harmless.

Claim 2 recites a formulation that is applied to a person's nasal passages, forming a thin film that adheres to the skin or tissue of his nasal passages. The formulation contains at least one cationic agent. Cationic agents create a positive electrostatic charge. The formulation also contains at least one biocidic agent (a biocide). Once applied to the skin or tissue, the thin film attracts oppositely charged particles, and holds them in place. The formulation then inactivates the harmful particles and renders them harmless.

Claim 6 depends from claim 2, and it incorporates all of the limitations and features of claim 2 by reference. Claim 6 recites that at least one cationic agent in claim 2 is Benzalkonium Chloride.

Claim 7 depends from claim 2, and it incorporates all of the limitations and features of claim 2 by reference. Claim 7 recites that at least one biocidic agent in claim 2 is Benzalkonium Chloride.

According to information supplied by Defendant, BlueWillow Biologics, Inc. ("BlueWillow"), sales of the asserted Nanobio® Protect product began January 2020 and continued through June 2021. BlueWillow continued receiving income from sales of the product through September 2021. The complaint in the present lawsuit was filed on February 10, 2021. All sales of this product and income received from the product by BlueWillow after January 2021 were made following the point when BlueWillow knew of the existence of the '802 Patent.

The complaint filed in this lawsuit included two exhibits (ECF 1-1 and 1-2) that reproduced portions of BlueWillow's website (*www.bluewillow.com/nanobio-protect*) as they existed on February 7, 2021. According to ECF 1-1 ("Exhibit 1"), the Nanobio® Protect product "can be used to help reduce germs on skin that can cause infections." The product is applied around the rim of the user's nose as well as inside the nostril using a

cotton swab. The Nanobio® Protect product consists of a oil-water nanoemulsion having "nano-droplets" that are "attracted to germs by electro-kinetic charge." "The droplets persist on skin for 4 or more hours, enabling long-lasting effectiveness." The website continues:

> *Nanobio® Protect kills germs via membrane disruption. Nanobio® Protect is comprised of positively charged droplets that are 300-600 nm in size. The droplets are attracted to negatively charged germs in the skin*
> .

The formation of an electrostatically charged thin film by the Nanobio® Protect product was confirmed experimentally by Trutek's experts (ECF 1-3 and 1-4). The website further states, "[t]he unique effectiveness of Nanobio® Protect is derived from BlueWillow's patented nanotechnology. Nanobio® Protect places the BZK antiseptic on the surface of the nano-droplets ..." BZK is BlueWillow's abbreviation for Benzalkonium Chloride. Benzalkonium Chloride is a known cationic agent and biocidic agent. A cationic agent produces a positive electrostatic charge. Therefore, the Nanobio® Protect product reads on claims 1, 2, 6, and 7 of the '802 Patent.

According to the Order issued by the Court (ECF 33), Plaintiff, Trutek Corp., submits this brief on claim construction issues, and respectfully requests that a Markman Hearing be scheduled and held by this Court.

RULES FOR CLAIM CONSTRUCTION

A. GENERAL RULES OF CONSTRUCTION

As far back as the late Nineteenth Century, the U.S. Supreme Court held that claim construction is within the province of the court. "Where the defense denies that the invention used by the defendant is identical with that included in the plaintiff's patent, the court defines the patented invention as indicated by the language of the claims; the jury judge whether the invention so defined covers the art or article employed by the defendant." *Coupe v. Royer*, 155 U.S. 565, 579 (1895). In *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 978 (1995), the Federal Circuit held, "in a case tried to a jury, the court has the power and obligation to construe as a matter of law the meaning of language used in the patent claim." "The decision that claim construction is properly viewed solely as a question of law is consistent with precedent of the Supreme Court and much of this court's precedent." *Id.* at 983. "Both this court and the Supreme Court have made clear that all elements of a patent claim are material, with no single part of a claim being more important or 'essential' than another." *Id.* at 988.

Patent claims are complex legal instruments. A claim may only be presented as a single sentence. "Each claim begins with a capital letter and ends with a period. Periods may not be used elsewhere in the claims except

for abbreviations." MPEP[1] § 608.01(m) citing *Fressola v. Manbeck,* 36 USPQ2d 1211 (D.D.C. 1995). Claims are usually long run-on sentences, which require patent practitioners to properly draft them. Certain terms have meanings that are different from their plain and ordinary meanings. As a whole, they are difficult for lay persons to understand. To enable a jury to make sense of a patent claim, the court should first interpret the claim as a whole prior to submitting it to the jury for consideration. "[W]e see the importance of uniformity in the treatment of a given patent as an independent reason to allocate all issues of construction to the court." *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996).

"The starting point for any claim construction must be the claims themselves," *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999), citing *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996); Cf. *Johnson Worldwide Assoc. Inc. v. Zebco Corp.*, 175 F.3d 985, 989 (Fed. Cir. 1999); *Teleflex Inc. v. Ficosa North America Corp.*, 299 F.3d 1313, 1314 (Fed. Cir. 2002).

After that, the rest of the intrinsic evidence, beginning with the specification and concluding with the prosecution history is consulted.

[1] "MPEP" is the acronym for "Manual of Patent Examining Procedure." This reference is a compendium of federal statutes and rules along with instructions to USPTO patent examiners as how to examine applications for patents.

Interactive Gift Express, Inc. v. Compuserve, Inc., 256 F.3d 1323, 1331 (Fed. Cir. 2001), *Vitronics* at 1582; *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995); aff'd 517 U.S. 370 (1996).

If the claim language is clear on its face, consideration of the other intrinsic evidence is limited to determining if the patentee intended to deviate from the clear language of the claims. *Interactive Gift* at 1331, quoting *Vitronics* at 1582, and "**...**if a patentee has relinquished [a] potential claim construction in an amendment to the claim or in an argument to overcome or distinguish a reference." *Interactive Gift* at 1331, citing *Elfay Mfg. v. Ebco Mfg. Co.*, 192 F.3d 973, 979 (Fed. Cir. 1999).

Where the claim language is not clear on its face, the intrinsic evidence is considered more fully, in order to resolve the lack of clarity. *Interactive Gift* at 1331.

Extrinsic evidence, such as dictionaries and the testimony of the inventor and technical experts, may be considered, but only for limited purposes. Such evidence, "**...**always may be admitted by the trial court to educate itself about the patent and the relevant technology**...**" *Mantech Environmental v. Hudson Environmental Services*, 152 F.3d 1368, 1373 (Fed. Cir. 1998); *Cf. Markman* at 981, *Pitney Bowes* at 1309. Courts should not however, rely upon extrinsic evidence to contradict the meaning of claim

language if that meaning is clearly discernible from the intrinsic evidence, (*Pitney Bowes* at 1308; *Vitronics* at 1583; *Bell & Howell Management Prods. Co. v. Altek Sys.*, 132 F.3d 701, 706 (Fed. Cir. 1997)), except for the very limited purpose of ensuring, "**...**that the claim construction it is tending to from the patent file is not inconsistent with clearly expressed plainly apposite, and widely held understandings in the pertinent technical field." *Pitney Bowes* at 1309.

There is always a heavy presumption that claim terms carry their ordinary and customary meanings. *CSS Fitness, Inc. v. Brunswick Corp.*, 288 F.3d 1359, 1366 (Fed. Cir. 2002); *Teleflex* at 1325; *Altiris, Inc. v. Symantic Corp.*, 318 F.3d 1363, 1369 (Fed. Cir. 2003).

Claims are always construed from the point of view of one who is skilled in the art. *Interactive Gift* at 1332.

B. RULES FOR CONSTRUCTION OF 35 U.S.C. § 112, para. 6, MEANS PLUS FUNCTION CLAIM LIMITATIONS

Pre-AIA 35 U.S.C. § 112, para. 6 provides that:

> *An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.*

The determination of whether claim language invokes § 112 (¶ 6) is an exercise of claim construction, and thus is appropriately decided by the Court as a matter of law in the context of a *Markman* hearing. *Wenger Mfg. v. Coating Mach. Sys.*, 239 F.3d 1225, 1231 (Fed. Cir. 2001).

The construction of claim limitations found to invoke § 112 (¶ 6) includes identifying the claimed function and determining the corresponding structures disclosed in the specification, both of which are questions of law. *IMS Tech., Inc. v. Haas Automation, Inc.*, 206 F.3d 1422, 1430 (Fed. Cir. 2000); Cf. *Chiuminatta Concrete Concepts, Inc. v. Cardinal Industries*, 145 F.3d 1303, 1308 (Fed. Cir. 1998).

CONSTRUCTION OF CLAIM ELEMENTS AND LIMITATIONS

As discussed in the previous section *supra*, if the claim language is clear on its face, consideration of the other intrinsic evidence is limited to determining if the patentee intended to deviate from the clear language of the claims. *Interactive Gift* at 1331, quoting *Vitronics* at 1582. Thus, the words of a claim must be given their plain meaning unless the applicant has provided a clear definition in the specification. When defining the terms in the claims for their plain meaning, extrinsic evidence such as dictionaries and scientific treatises may prove necessary.

Plaintiff's proposed constructions are in each case based upon the claims, the specification of the '802 Patent, and its prosecution history. Construction of any claim must be based upon consideration of the claim as a whole, rather than of the claim elements individually. However, it is important that this Court examine the various claim elements in its claim construction effort.

In order to explain the meaning of the claims and their limitations, Plaintiff refers to the Claim Chart in Exhibit A.

A. CLAIM ELEMENTS

Claim 1 is an independent method claim that recites electrostatically inhibiting infection of an individual from inhaling harmful particles using a specific formulation. Claim 2 is an independent claim that recites a formulation used to inhibit infection of an individual from inhaled airborne particles.

1. Electrostatically (Appears in Claims 1 & 2)

The word, "electrostatically," refers to "static electricity" and utilizing electrically charged particles. *Merriam-Webster Dictionary*. The Summary of the Invention Section of the '802 Patent Specification (at 3:32-3:40) refers to "an electrostatically charged composition ... when applied to a surface, creates an electrostatic field." It is well known that in an electrostatic field,

oppositely charged particles attract each other, and similarly charged particles repel each other.

2. Electrostatically Attracting (Appears in Claims 1 & 2)

In claim 2, the element is, "electrostatically attracts." As discussed *supra*, opposite static charged particles attract each other. Here, once applied, the formulation exhibits a static charge, while the "harmful particles" exhibit an opposite charge. Thus, the applied formulation attracts the harmful particles. The Summary of the Invention section of the Specification discloses (at 3:35-3:38) that the "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped ..."

3. Electrostatically Inhibiting (appears in claims 1 & 2)

The word, "inhibiting," means (1) to prohibit from doing something or (2) to hold in check. *Merriam-Webster Dictionary*. The preambles of claims 1 and 2 refer to "electrostatically inhibiting harmful particulate matter from infecting an individual..." The meaning of this expression is using an electrostatic field to attract or repel harmful particles. The recited formulation then prohibits the harmful particles from infecting the individual. The Abstract of the Specification states that microorganisms coming in contact

with the substrate or skin are rendered less harmful. The Summary of the Invention section discloses (at 3:35-3:40) that the "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless."

4. Thin Film (appears in claims 1 & 2)

Any liquid or gel material applied to the nostrils will form a thin film on the skin or tissue of the nasal passages. That film adheres to the skin or tissue to a greater or lesser degree depending on the material's viscosity. For example, a less viscous liquid (such as a sprayed or applied aqueous saline solution) gushes out of the individual's nose, but the skin still remains wet. A more viscous material, such as a gel will remain on the skin once applied and will not drip out.

5. Holds the particulate matter in place (appears in claims 1 & 2)

As used in the claims, the phrase means that once the harmful particulate matter is attracted to the thin film, they are trapped and restricted or prevented from dislodging or migrating away from the thin film.

6. Adhesion (appears in claims 1 & 2)

There are two relevant dictionary definitions of ***adhesion***:

a) steady or firm attachment; and

b) the molecular attraction exerted between the surfaces of bodies in contact.

(*Merriam-Webster Dictionary*.)

As used in the claims, once an oppositely charged harmful particle is attracted to the charged thin film, that harmful particle will stick to the thin film. It becomes "electrostatically trapped and held thereto." ('802 Patent at 3:38.) Further, the adhesion is adjusted "to permit said thin film to stick to the skin or tissue." (*Id.* at 10:27 and 10:38.)

7. Cohesion (appears in claims 1 & 2)

There are two relevant dictionary definitions of ***cohesion***.

a) the act of sticking together tightly; and

b) molecular attraction by which the particles of a body are united throughout the mass.

(*Merriam-Webster Dictionary*.)

Adhesion is the tendency of dissimilar particles or surfaces to cling to one another. ***Cohesion*** refers to the tendency of similar or identical particles or surfaces to cling to one-another.

As used in the claims, cohesion of the formulation is adjusted so that its molecular ingredients fit so tightly together so as to restrict harmful particles from penetrating into the skin or tissue of the individual.

8. Adequate Impermeability (appears in claims 1 & 2)

The dictionary definition of ***impermeability*** is "not permitting passage (as of a fluid) through its substance." (*Merriam-Webster Dictionary*.). The dictionary definition of ***adequate*** is "sufficient for a specific need or requirement." (*Id.*) Claims 1 and 2 state specific "needs and requirements."

The preamble of method claim 1 states in part, "... *inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to the nasal passages of the individual in a thin film* ..." Element (b) of claim 1 states in part, "... *holding the particulate matter in place ... by adjusting the cohesion of the formulation to provide adequate permeability to the thin film* ..." Finally, Element (c) states the purpose of the claim as, "... *render said particulate matter harmless.*"

The preamble of formulation claim 2 and claim Elements (b) and (c) state similar needs and requirements as claim 1, above.

Thus, ***adequate impermeability***, as used in the claims, refers to the thin film inhibiting harmful particles from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages.

9. Cationic Agent (appears in claims 2 & 6)

A ***cationic agent*** is a chemical substance that creates a positive electrostatic charge.

10. Biocidic Agent (appears in claims 2 & 7)

Also known as a ***biocide***, a ***biocidic agent*** is a chemical substance that destroys or inhibits the growth or activity of living organisms. (*Merriam-Webster Dictionary.*)

11. Inactivates or Inactivating (appears in claims 1 & 2)

The relevant dictionary definition of ***inactive*** is "*biologically inert especially because of the loss of some quality (such as infectivity or antigenicity*.) " (*Merriam-Webster Dictionary.*)

The dictionary definition of ***inactivates*** and ***inactivating*** is to make inactive (*Merriam-Webster Dictionary*). The definition specifically relates to "chemicals to inactivate viruses.

B. INTERPRETATION OF THE CLAIMS IN THEIR ENTIRETY

The claims of the '802 Patent that are at issue in this action are claims 1, 2, 6, and 7.

1. Effect of the Preamble

The preamble is a general statement of the type of claim (consistent with 35 U.S.C. § 101), and it may include a statement of use or functionality.

Examples of the type of claim might be, *inter alia*, "a method," "a process," "a manufactured article," or a "chemical compound."

"[A] claim preamble has the import that the claim as a whole suggests for it." *Bell Communications Research, Inc. v. Vitalink Communications Corp.*, 55 F.3d 615, 620 (Fed. Cir.1995). "If the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). A use or a purpose for an invention cannot be patented. "If the body of a claim fully and intrinsically sets forth all of the limitations of the claimed invention, and the preamble merely states, for example, the purpose or intended use of the invention, rather than any distinct definition of any of the claimed invention's limitations, then the preamble is not considered a limitation and is of no significance to claim construction." *Id.* "The effect preamble language should be given can be resolved only on review of the entirety of the patent to gain an understanding of what the inventors actually invented and intended to encompass by the claim. *Corning Glass Works v. Sumitomo Elec. U.S.A., Inc.*, 868 F.2d 1251, 1257 (Fed. Cir. 1989)." The preamble of a claim has "life, meaning, and vitality" only when its language

recites structural limitations not present in the body of the claim, but upon which the body of the claim relies.

The preamble of independent method claim 1 recites, "electrostatically inhibiting harmful particulate matter from infecting an individual through inhalation wherein ***a formulation*** is applied to ***skin or tissue of nasal passages*** of the individual in ***a thin film***." Here, in the preamble, ***a formulation*** is first mentioned. However, application of ***the formulation*** is implied in Element (b) therein because it is referenced as an antecedent basis in the preamble. ('802 Patent at 10:26-30.) Similarly, the aforementioned ***thin film*** in Element (b) is referenced as an antecedent basis in the preamble. *Id.* Further, Element (b) recites that ***the thin film*** adheres to ***the skin or tissue***. Once again, ***the skin or tissue*** references "nasal passages of the individual." In addition, the reference to inhalation of "harmful particles" translates into Element (b) as "particulate matter", and into Element (c) as rendering "said particulate matter harmless." Without reference to the claim's preamble, the entire claim becomes indefinite under 35 U.S.C. § 112(b). Thus, the preamble of claim 1, adds "life, meaning, and vitality" to the claim, and said preamble must be considered as a claim limitation during claim construction.

Similarly, in independent formulation claim 2, the limitation is recited, "inhibiting harmful particulate matter from infecting an individual through

inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film." As in claim 1, the preamble recites ***harmful particulate matter***, ***the formulation***, ***skin or tissue of nasal passages***, and ***thin film***. As argued for claim 1 *supra*, these terms form an antecedent basis for their corresponding terms in Elements (a) through (c) of the claim body. Without reference to the claim's preamble, the entire claim becomes indefinite under 35 U.S.C. § 112(b). Thus, the preamble of claim 2, adds "life, meaning, and vitality" to the claim, and said preamble must be considered as a claim limitation during claim construction.

2. Effect of the transitional phrase, "comprising"

Claims 1 and 2 are divided into sub-sections (a), (b), and (c), respectively. Both claims use the transitional phrase, "comprising." Transitional phrases in patent law have very specific legal meanings that are different from their plain and ordinary usage. MPEP § 2111.03 states:

> *The transitional term "comprising," which is synonymous with "including," "containing," or "characterized by," is inclusive or open-ended and does not exclude additional, unrecited elements or method steps.*

Citing *Mars Inc. v. H.J. Heinz Co.*, 377 F.3d 1369, 1376, 71 USPQ2d 1837, 1843 (Fed. Cir. 2004).

MPEP § 2111.03 continues:

> *"Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements*

> *may be added and still form a construct within the scope of the claim.*

Citing *Moleculon Research Corp. v. CBS, Inc.*,793 F.2d 1261, 229 USPQ 805 (Fed. Cir. 1986); *In re Baxter,* 656 F.2d 679, 686, 210 USPQ 795, 803 (CCPA 1981); *Ex parte Davis*, 80 USPQ 448, 450 (Bd. App. 1948).

Construction of a patent claim requires consideration of the claim as a whole – not just the individual elements taken separately. A transitional phrase *segues* from the claim's preamble to the body of the claim. The body of the claim consists of a series of elements that limit the claim type stated in the preamble.

Both independent claims 1 and 2 contain the transitional phrase, "comprising." When performing a construction of these claims, all of the elements following the transitional phrase must be considered to be essential, even though additional elements may be added.

The term, "wherein," provides an additional limitation on an element in the body of the claim. Any limitation on a claimed element serves to narrow the scope of protection for the claim.

With these principles in mind, independent claim 1 recites a method (or process), while independent claim 2 recites a formulation (or manufactured article. The stated purpose or stated use for the inventions of both claims is, "electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation." While claim 1 uses a formulation, claim

2 recites the formulation itself. In both claims, the formulation is applied to the skin or tissue of the nasal passages of the individual in a thin film.

3. Claim 1

In method claim 1, the process of Element (a) recites, "*electrostatically attracting the particulate matter to the thin film.*" A shorthand notation for this process is ***attracting***. The thin film is catching the particles using electrostatic attraction.

The process of Element (b) is ***holding***. Element (b) recites, "*holding the particulate matter in place ...*" The formulation does this by "***adjusting adhesion*** *of the thin film to permit said thin film to stick to the skin or tissue and by* ***adjusting the cohesion*** *to provide adequate impermeability to the thin film.*" By doing this, the particulate matter is held in place unable to dislodge or migrate to the skin or tissue of the individual's nasal passages.

The process of Element (c) is ***inactivating***. Element (c) recites, "*inactivating the particulate matter by* ***adding at least one ingredient*** *that would* ***render said particulate matter harmless***."

The process of ***attracting*** is performed by electrostatically attracting the particulate matter to the thin film and binding it thereto.

The process of ***holding*** is performed by ***adjusting to adhesion*** to permit the thin film to stick to the skin or tissue, and by ***adjusting the cohesion*** to

provide adequate impermeability. These two sub-elements are essential to Element (b) of the claim.

The process of ***inactivating*** is rendering the particulate matter harmless by adding at lease one ingredient to do this. The sub-element of adding the ingredient is essential to the claim.

Thus, although additional steps may be added, the method claim 1 breaks down to three essential steps, *i.e.*, (a) ***attracting***, (b) ***holding***, and (c) ***inactivating***.

4. Claim 2

Claim 2 recites a formulation, which is a manufactured article that is applied to the skin or tissue of an individual's nasal passages in a thin film. The formulation comprises:

- at least one cationic agent and
- at least one biocidic agent.

Both of these are essential ingredients. Moreover, the formulation is fabricated with the above ingredients along with additional ingredients to exhibit the following properties. The applied thin film ***attracts***, ***holds***, and ***inactivates*** harmful particulate matter. Most airborne harmful particles possess a negative electrostatic charge. The cationic agent of the formulation provides it with a positive charge. Thus, harmful particles are attracted to the

thin film. The additional ingredients adjust the adhesion of the thin film so as to stick to the skin or tissue of the nasal passages. The particles are held fast to the film by virtue of their opposite charges and are prevented from contacting the skin or tissue by impermeability of the film. Claim 6

A dependent claim is one that references another preceding or earlier claim in the same patent. As such, it must not be read stand-alone. It must be integrated with its base claim. All of the limitations present in the base claim are incorporated by reference into the claim at issue.

Claim 6 references the formulation of claim 2. Thus, its construction requires it to be read as a modified claim 2. Here, claim 2 is modified by specifically citing one of the cationic agents of claim 2 as benzalkonium chloride, which is a known cationic agent.

5. Claim 7

Claim 7 references the formulation of claim 2. Thus, its construction requires it to be read as a modified claim 2. Here, claim 2 is modified by specifically citing one of the biocidic agents of claim 2 as benzalkonium chloride, which is a known biocide.

DISPUTED CLAIM TERMS

The following table was included in "Defendant BlueWillow Biologics, Inc.'s Initial Disclosure On Claim Construction," sent to Plaintiff on August

17, 2022. The table (copied below) presents those claim terms presented by Trutek, which are disputed by BlueWillow.

Claim Term	BlueWillow's Proposed Construction
Preamble of claim 1 (claims 1 and 2)	The preamble of claim 1 is limiting.
Preamble of claim 2 (claims 1 and 2)	The preamble of claim 1 is limiting.
"electrostatically inhibiting" (claims 1 and 2)	The claim term and/or phrase renders claims 1 and2 indefinite under 35 U.S.C. § 112, paragraph 2.
"electrostatically attracting" (claims 1 and 2)	The claim term and/or phrase renders claims 1 and2 indefinite under 35 U.S.C. § 112, paragraph 2.
"adequate impermeability" (claims 1 and 2)	The claim term and/or phrase renders claims 1 and2 indefinite under 35 U.S.C. § 112, paragraph 2.
"render[s] said particulate matter harmless" (claims 1 and 2)	The claim term and/or phrase renders claims 1 and2 indefinite under 35 U.S.C. § 112, paragraph 2.

In its Initial Disclosure On Claim Construction, BlueWillow presented no reasoning to support its allegations of indefiniteness except to say that these terms, "when read in light of the specification and prosecution history, fails to inform with reasonable certainty those skilled in the art about the scope of the invention. ... These terms and/or phrases are general in nature, and rely on terms that are both relative and subjective, rendering the claims indefinite as to the scope of the claimed invention." In so saying, BlueWillow relied on *Nautilus, Inc. v. Biosig Instruments, Inc.*, 572 U.S. 898 (2014). In that case, the Supreme Court held that, "a court will not find a patented claim indefinite

unless the claim interpreted in light of the specification and the prosecution history fails to 'inform those skilled in tha art about the scope of the invention with reasonable certainty.'" *Id.* at 1689.

The effect of the preambles of claims 1 and 2 was discussed *supra* on pages 16-18 in Section III(B)(1) of this brief. In that discussion, it was stated that, "[i]f the claim preamble, when read in the context of the entire claim, recites limitations of the claim, or, if the claim preamble is 'necessary to give life, meaning, and vitality' to the claim, then the claim preamble should be construed as if in the balance of the claim." *Pitney Bowes, Inc. v. Hewlett-Packard Co.*, 182 F.3d 1298, 1305 (Fed. Cir. 1999). Plaintiff asserted that the preamble introduced terms in such manner that were it to be ignored, recitation of those terms in the body of the claim would render them indefinite. Thus, because those claim term limitations first appear in the preamble, the preamble must be "construed as if in the balance of the claim."

It is unclear what BlueWillow means when it states that, "the preamble of claim [1 or 2] is limiting." However, Trutek agrees with BlueWillow's allegation if it is interpreted to mean that the limitations of these claim preambles are "construed as if in the balance of the claim."

Without explanation, BlueWillow alleges that the terms, electrostatically inhibiting, electrostatically attracting, adequate

impermeability, and render[s] said particulate matter harmless are indefinite under 35 U.S.C. § 112(b) or pre-AIA 35 U.S.C. § 112, Second Paragraph.

Plaintiff's constructions of the following disputed terms were discussed earlier:

Term	**Section**	**Page**
"electrostatically inhibiting"	III(A)(3)	12
"electrostatically attracting"	III(A)(2)	11
"adequate impermeability"	III(A)(8)	14

The term "electrostatically" (Section III(A)(1) on page 11) is given its plain and ordinary dictionary meaning. That section discusses the well-known scientific principle that an electrostatic field utilizes electrically charged particles and that oppositely charged particles attract each other.

The term "electrostatically attracting" (Section III(A)(2) on page 11) refers to that well-known scientific principle. The specification describes a "formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped."

The term "electrostatically inhibiting" (Section III(A)(3) on page 12) is taken from the specification to mean that, "the formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged particulates (including microorganisms) in the vicinity of the surface are

electrostatically trapped, held thereto, and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless."

Originally submitted independent claims 1, 2, and 8 of the subject patent application used the term "electrostatically preventing." In a USPTO office action dated August 25, 2011, the Examiner rejected these claims under 35 U.S.C. § 112, First Paragraph. The Examiner stated:

> *Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same, (see claims 1, 2 and 8; and thus the claims dependent therefrom). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.*
>
> *In order to overcome the rejection set forth infra, it is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.*

A copy of the above referred office action is attached hereto as Exhibit C. Clearly, the examiner understood the meaning of the terms "electrostatically preventing" and "electrostatically inhibiting." The examiner rejected the term "electrostatically preventing" because the "specification does not enable any person skilled in the art to ... make and use the invention

commensurate in scope with these claims." According to the examiner, the suggested amendment remedies the defect. Thus, a person having ordinary skill in the art would understand the term, "electrostatically inhibiting."

The claim term, "render[s] said particulate matter harmless," finds support in the specification, which discusses a formulation, "which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electro statically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless." (*At* 3:35.) Thus the term, "render[s] said particulate matter harmless," refers to one or more microorganisms being captured, killed, and inactivated. A person having ordinary skill in the art would understand this construction.

The term, "adequate impermeability" (Section III(A)(8) on page 14) refers to thin film holding harmful particles in place and inhibiting them from penetrating the thin film and contacting the skin or tissue of an individual's nasal passages. This is done by varying the concentration of ingredients (such as a surfactant, a thickener, and a binder ('802 Patent *at* 5:9-13)) thereby adjusting the adhesion and cohesion of the thin film. The particles are held in place by making the thin film impermeable. Here, the term "impermeable" is

given its plain and ordinary meaning. This would be understood by a person having ordinary skill in the art.

The term "adequate impermeability" uses a term of degree (*i.e.*, adequate). "Claim language employing terms of degree has long been found definite where it provided enough certainty to one of skill in the art when read in the context of the invention." *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1370 (Fed. Cir. 2014) (citing *Eibel Process Co. v. Minnesota & Ontario Paper Co.*, 261 U.S. 45, 65-66 (1923) (finding "substantial pitch" sufficiently definite because one skilled in the art 'had no difficulty ... in determining wheat was the substantial pitch needed' to practice the invention.)). Thus, when a term of degree is used in the claim, the examiner should determine whether the specification provides some standard for measuring that degree. *Hearing Components, Inc. v. Sure Inc.*, 600 f.3d 1357, 1367 (Fed. Cir. 2010); *Enzo Biochem, Inc. v. Appelera Corp.*, 399 F.3d 1325, 1332 (Fed. Cir. 2010); *Seattle box Co., Inc. v. Crating & Packaging, Inc.*, 731 F.2d 818, 826 (Fed. Cir. 1984). Here, the specification of the '802 Patent provides ten examples (Tables 1 - 10) of formulations that all function as in the claims. The formulations each contain ingredient compositions the concentration of which is given in ranges. The actual ingredient concentrations need to be adjusted by one having ordinary skill in the art (*i.e.*,

a formulator) to have the desired characteristics of adhesion of the thin film along with its tackiness to capture and hold the harmful particles, thus providing adequate impermeability. While this would require some experimentation, for a person having ordinary skill in the art, that experimentation would not be undue. Further, as indicated in the USPTO office action (Exhibit C), the examiner considered whether, and in allowing the application, determined that the claims, as a whole, would enable a person of ordinary skill "to make and use the invention as commensurate in scope with these claims."

Therefore, based on the foregoing arguments, BlueWillow's allegations of indefiniteness fail.

Dated: September 8, 2022

Respectfully Submitted,

Keith Altman, Esq.
Law Office of Keith Altman
33228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
Telephone: (987) 987-8929
keithaltman@kaltmanlaw.com
Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

TRUTEK CORP.,

Plaintiff,

v.

BLUEWILLOW BIOLOGICS, INC.,

Defendants.

Case No. 2:21-cv-10312

Hon. Stephen J. Murphy, III

CERTIFICATE OF SERVICE

I certify that on September 8, 2022, I served the foregoing Plaintiff's Initial Brief on Claim Construction Issues for Markman Hearing upon all parties herein by filing copies of same using the ECF System.

Keith Altman, Esq.
Law Office of Keith Altman
33228 West 12 Mile Road, Suite 375
Farmington Hills, Michigan 48334
Telephone: (987) 987-8929
keithaltman@kaltmanlaw.com
Attorneys for Plaintiff

EXHIBIT A

Trutek Corp. v. BlueWillow Biologics, Inc.
Civ. Action No. 2:21-cv-10312-SJM-RSW

CLAIM CHART

CLAIM 1

PATENT CLAIM LANGUAGE	INTERPRETATION
A method for electrostatically **inhibiting harmful particulate matter** from infecting an individual through nasal inhalation wherein **a formulation** is **applied to skin or tissue of nasal passages** of the individual in **a thin film**, said method **comprising**:	Claim 1 is a method claim, which recites preventing an individual from becoming infected from inhaling harmful airborne contaminant particles. A formulation, which exhibits a static electrical charge, is applied to the individual's nostrils, and it forms a statically charged thin film thereon.
a) electrostatically **attracting** the particulate matter to the thin film;	The formulation's electrostatically charged thin film attracts oppositely charged harmful particles.
b) **holding** the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,	The thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film having a electrostatic charge captures and holds the oppositely charged harmful particles (that were attracted to it) in place.
c) **inactivating** the particulate matter by adding at least one ingredient that would render said particulate matter harmless.	The formulation contains at least one ingredient that inactivates the captured harmful particles and renders one or more of them harmless by killing or inactivating them..

Trutek Corp. v. BlueWillow Biologics, Inc.
Civ. Action No. 2:21-cv-10312-SJM-RSW

CLAIM CHART
CLAIM 2

PATENT CLAIM LANGUAGE	INTERPRETATION
A formulation for electrostatically **inhibiting harmful particulate matter** from infecting an individual through nasal inhalation wherein the formulation is **applied to skin or tissue of nasal passages** of the individual in **a thin film**, said formulation **comprising** at least one **cationic agent** and at least one **biocidic agent**, and wherein said formulation, once applied:	A formulation, when applied to a person's nostrils, forms a thin film therein and prevents that person from becoming infected from inhaling harmful airborne contaminant particles. The formulation contains at least one cationic agent. A cationic agent produces a positive electrostatic charge. The formulation also contains a biocide.
a) electro statically **attracts** the particulate matter to the thin film;	Oppositely statically charged harmful particles are attracted to the formulation's thin film. The thin film is positively charged (cationic), and most harmful particles are negatively charged.
b) **holds** the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,	The thin film formulation is designed to adhere to the skin or tissue of the nostrils and to be impermeable. The thin film having a electrostatic charge captures and holds the oppositely charged harmful particles (that were attracted to it) in place.
c) **inactivates** the particulate matter and renders said particulate matter harmless.	The biocide in the formulation inactivates the captured harmful particles and renders them harmless.

Trutek Corp. v. BlueWillow Biologics, Inc.
Civ. Action No. 2:21-cv-10312-SJM-RSW

CLAIM CHART

CLAIM 6

PATENT CLAIM LANGUAGE	INTERPRETATION
The formulation of claim **2** wherein	This claim depends from claim 2. All of the features and limitations of claim 2 are incorporated by reference into this claim.
the at least one cationic agent is Benzalkonium Chloride.	The "at least one cationic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known cationic agent.

CLAIM 7

PATENT CLAIM LANGUAGE	INTERPRETATION
The formulation of claim **2** wherein	This claim depends from claim 2. All of the features and limitations of claim 2 are incorporated by reference into this claim.
the at least one biocidic agent is Benzalkonium Chloride.	The "at least one biocidic agent" referred to in claim 2 is Benzalkonium Chloride, which is a known biocidic agent.

EXHIBIT B

US008163802B2

(12) **United States Patent**
Wahi

(10) **Patent No.: US 8,163,802 B2**
(45) **Date of Patent: Apr. 24, 2012**

(54) **ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD**

(75) Inventor: **Ashok Wahi**, Hillsborough, NJ (US)

(73) Assignee: **Trutek Corp.**, Hillsborough, NJ (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 316 days.

(21) Appl. No.: **12/467,271**

(22) Filed: **May 16, 2009**

(65) **Prior Publication Data**

US 2010/0004337 A1 Jan. 7, 2010

Related U.S. Application Data

(60) Provisional application No. 61/085,855, filed on Aug. 3, 2008, provisional application No. 61/078,478, filed on Jul. 7, 2008.

(51) **Int. Cl.**
A61K 31/198 (2006.01)
A61K 31/14 (2006.01)

(52) **U.S. Cl.** **514/564**; 514/643

(58) **Field of Classification Search** 514/564, 514/643; 128/206.11
See application file for complete search history.

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2003/0223934	A1	12/2003	Wahi

Primary Examiner — Raymond Henley, III
(74) *Attorney, Agent, or Firm* — Stanley H. Kremen

(57) **ABSTRACT**

A product to reduce and method of reducing the risk of inhalation of harmful substances by applying a formulation composition to a substrate or the skin in close proximity of one or more nostrils. This formulation, when applied creates an electrostatic field having a charge. The electrostatic field attracts airborne particulates of opposite charge to the substrate that are in close proximity to the substrate close to the skin and a biocidic agent renders microorganisms coming in contact the substrate or skin less harmful.

23 Claims, No Drawings

ELECTROSTATICALLY CHARGED MULTI-ACTING NASAL APPLICATION, PRODUCT, AND METHOD

CROSS REFERENCE TO RELATED APPLICATIONS

a) The Present application is the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/085,555 (the '555 application) filed on Aug. 3, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '555 application.

b) The Present application is also the non-provisional counterpart of my pending U.S. Provisional Patent Application Ser. No. 61/078,478 (the '478 application) filed on Jul. 7, 2008 which is incorporated by reference in its entirety herein. The Present application claims the benefit of and priority to said '478 application.

c) The Present application is likewise related to my prior U.S. Provisional Patent Application Ser. No. 60/570,103 (the '103 application) filed on May 12, 2004 (now expired), and which is incorporated by reference in its entirety herein. The '478 application provides a virtually identical disclosure to the '103 application.

d) Furthermore, the Present application is related to my pending U.S. Provisional Application Ser. No. 61/078,472 filed on Jul. 7, 2008, which is incorporated by reference in its entirety herein.

e) The Present application is also related to my prior U.S. Provisional Patent Application Ser. No. 60/598,462 filed on Aug. 3, 2004 (now expired), and which is incorporated by reference in its entirety herein.

f) The Present application is additionally related to my U.S. Pat. No. 5,468,488, entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT AND METHOD" issued on Nov. 21, 1995. This patent is incorporated by reference in its entirety herein.

g) The Present application is further related to my U.S. Pat. No. 5,674,481, entitled "ELECTROSTATICALLY CHARGED NASAL TOPICAL APPLICATION PRODUCT" issued on Oct. 7, 1997. This patent is incorporated by reference in its entirety herein.

h) The Present application is moreover related to my U.S. Pat. No. 6,844,005 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" issued on Jan. 18, 2005. This patent is incorporated by reference in its entirety herein.

i) Finally, this application is furthermore related to US Non-Provisional Utility patent application Ser. No. 10/082,978 entitled "ELECTROSTATICALLY CHARGED NASAL APPLICATION PRODUCT WITH INCREASED STRENGTH" filed on Feb. 25, 2002. This patent application is incorporated by reference in its entirety herein.

FIELD OF THE INVENTION

The Present Invention relates to the field of protective compositions against assault by various irritants and noxious substances as well as against assault by assorted microorganisms that typically gain entry into the body through the airway and/or nasal mucosa. The Present Invention also relates to anti-viral, anti-bacterial, and anti-microbial products and methods that involve the use of products heretofore developed for restricting the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. This reduced the inflow of airborne contaminants to the nasal passages by capturing the contaminants and keeping them from entering the body. In the present invention, these electrostatically charged nasal application products capture and hold the contaminants including viruses, bacteria, and other harmful microorganisms or toxic particulates, inactivate them dermally outside the body and render them harmless.

BACKGROUND OF THE INVENTION

The nasal passages and nasal mucosa serve as body entry points for a wide variety of noxious and toxic substances. The body's immune system responds with certain relatively harmless irritants to the nasal passages and airways with reflex responses such as coughing and sneezing. This merely reintroduces the irritants into the environment. However, when the irritant comprises microorganisms, especially those that reproduce within the body and that are transmitted by coughing and sneezing, others may become infected. When a person feels a cough or a sneeze coming on, he merely covers his nose and mouth. However, if that person is contagious, this action does little to prevent others from also becoming infected. Furthermore, the use of a tissue or handkerchief for this purpose is extremely inefficient. This limits the protection of an individual from becoming infected or infecting others.

Other means of dealing with preventing inhalation of harmful or irritating substances or of infections agents include wearing facemasks to filter out these irritants. An example of this is the simple dust mask, typically found in the hardware store or medical supply store. However, even these are inadequate and inefficient. In many localities, during flu season, one can see a large number of people wearing these dust masks in public places. The dust masks are now known to be ineffective. Another example of this preventative method is the gas mask, which is more efficient than the dust mask. Yet, even gas masks are not highly efficient with respect to microscopic and sub-microscopic microorganisms. Furthermore, they are extremely cumbersome and cannot generally be used during normal day-to-day activities.

Patents such as U.S. Pat. No. 6,844,005 describe electrostatically charged compositions that may be applied externally in the vicinity of the nostril and attract oppositely charged materials that would otherwise be inhaled. However, those compositions simply create an electrostatic field that helps to filter out oppositely charged materials. While this action may offer suitable protection against particles that are inhaled passively, they suffer from the fact that they cannot completely deal with particulates that have their own internal means of overcoming the electrostatic forces, such as microorganisms that are motile within the air stream. Furthermore, actions by the person having those electrostatic compositions in the vicinity of the nostrils can sufficiently displace the offending particles or organisms, especially in such instances as blowing or wiping the nose, so that particles that were held captive by the former compositions could become dislodged, again set free, and be inhaled.

OBJECTS OF THE INVENTION

It is therefore an object of the invention to provide a composition that can be readily applied to the exterior region around the nostril and/or slightly inside the edge of the nostril or near the vicinity of the source of release with method and compositions capable of capturing particulates and microorganisms.

It is another object of the invention to have the capability to hold it for a duration from being dislodged in to the air stream again.

It is a further object of the invention to provide a composition that can be applied near the vicinity of the source of release or to the area around the exterior of and/or slightly inside the edge of the nostril that will inactivate, kill, or render harmless a microorganism, which has been captured and held by the composition.

It is yet another object of the invention to provide a composition that can be applied to a filter substrate for improving the substrates ability to trap and hold particulates and microorganisms and to simultaneously inactivate, kill, or render harmless the microorganisms so trapped. Such filter substrate could be placed in the close proximity of the skin near the path of inhalation, near the source of release of such particulates while the inhaler is at a distance or both.

It is still another object of the invention to provide a method of prophylactically preventing or of substantially reducing the risk of infection by an infectious agent without the utilization of ingested antiviral and/or antibacterial agents.

Yet other objects of the invention will be apparent to those of ordinary skill once having benefit of the instant disclosure. In all of the foregoing objects, the deficiencies of the previously mentioned prior art are overcome by the teachings of this invention.

SUMMARY OF THE INVENTION

These and other objects of the invention are unexpectedly achieved by an electrostatically charged composition having at least one polymeric quaternary compound in an aqueous or non-aqueous based formulation, which when applied to a surface, creates an electrostatic field such that oppositely charged airborne particulates (including microorganisms) in the vicinity of the surface are electrostatically trapped, held thereto and one or more of the microorganisms so captured is neutralized, killed, inactivated, and rendered harmless.

DETAILED DESCRIPTION OF THE INVENTION

The present invention relates to anti-microorganism, anti-viral/anti-bacterial products and methods that involve the use of products that restrict the flow of airborne contaminants into the nasal passages by creating an electrostatic field in an area near about the nasal passages. Additionally, in the present invention, these electrostatically charged nasal application products are used to hold the contaminants including micro-organisms, viruses, bacteria, and other harmful or toxic particulate outside the body and render them harmless.

Emergencies of Anthrax lead to the concept of avoidance of inhaling airborne microscopic and sub-microscopic contaminants. It is the intention of the Present Invention to filter and render harmless materials such as anthrax spores, human corona virus, smallpox virus, influenza virus, avian flu virus, swine flu virus, rhino virus, and other biological or chemical elements/toxins/irritants, and the like, prior to their entering the nasal passages.

Airborne microorganisms are a major cause of respiratory ailments in humans, causing allergies, asthma, and pathogenic infections of the respiratory tract. Airborne fungal spores are also important agents that spread diseases. Respiratory diseases cause many fatalities and are a cause of great concern. During a sneeze, millions of tiny droplets of water and mucus are expelled at a high velocity. The droplets contain viral particles and/or bacteria. This is a means of transmission of several diseases by inhaled airborne particles as follows:

VIRAL DISEASES (virus type in brackets)	BACTERIAL DISEASES (bacterial name in brackets)
Chickenpox (Varicella)	Whooping cough (*Bordetella pertussis*)
Flu (Influenza)	Meningitis (*Neisseria* species)
Measles (Rubeola)	Diphtheria (*Corynebacterium diphtheriae*)
German measles (Rubella)	Pneumonia (*Mycoplasma pneumoniae*, *Streptococcus* species)
Mumps (Mumps)	Tuberculosis (*Mycobacterium tuberculosis*)
Smallpox (Variola)	Anthrax (*Anthracsis* bacterium)
SARS (Human Corona)	

Diseases caused by environmental particulates include, but are not limited to the following:

ENVIRONMENTAL PARTICULATE DISEASES	SOURCE
Psittacosis (*Chlamydia psittaci*)	Dried, powdery droppings from infected birds (parrots, pigeons, etc.)
Legionnaire's disease (*Legionella pneumophila*)	Droplets from air-conditioning systems, water storage tanks, etc., where the bacterium grows.
Acute allergic alveolitis (various fungal and actinomycete spores)	Fungal or actinomycete spores from decomposing organic matter (composts, grain stores, hay, etc.)
Aspergillosis (*Aspergillus fumigatus*, *A. flavus*, *A. niger*)	Fungal spores inhaled from decomposing organic matter.
Histoplasmosis (*Histoplasma capsulatum*)	Spores of the fungus, in old, weathered bat or bird droppings.
Coccidioidomycosis (*Coccidioides immitis*)	Spores in air-blown dust in desert regions (Central, South and North America) where the fungus grows in the soil.

To accomplish the present invention, a formulation having at least one polyquaternary ammonium compound is prepared, such compounds, alone or together capable of creating an electrostatic field on and around a surface to which it is applied, including surfaces such as skin, textile (woven and non-woven), and hard surfaces, such as floors, walls, wood, metal, plastic, etc. The formulation is generally aqueous based, but may include non-aqueous solvents used which are compatible with the other formulation components and the application surface to which it is applied. Preferably, the formulation is an aqueous formulation. In addition to the polyquaternary ammonium compound, the composition includes at least. Furthermore, the composition may contain, but is not required to contain various thickeners, gellants, fragrances, colorants, emollients, humectants, and generally other suitable components that are compatible with the end use application and the other components of the formulations. Thus, a composition of the invention that is intended to be applied to a filter substrate that is perhaps used as a mask with an additional liner between a user and the filter substrate may utilize materials that would not be compatible with direct contact with skin, although it is preferable that all of the components are compatible with direct application to the skin as a means of limiting reaction due to inadvertent contact between the composition and the skin.

A formulation of the invention comprises:

water,

at least one quaternary thickener,

a preservative,
a conditioner,
an emulsifier,
a biocidic agent, and
a neutralizing agent added to adjust and achieve a pH in the range of 5.0 to 6.8.

It may further comprise without limitation a combination of the following:
a surfactant,
a thickener,
an emollient,
a humectant, and
a binder.

In an exemplary embodiment of such a formulation, a quaternary thickener may comprise without limitation, at least one of the following:
Polyquaternium-10
Polyquaternium-22
Polyquaternium-67
Polyquaternium-70
Polyquaternium-72
Polyquaternium-88
Cocodimonium Hydroxypropyl Hydrolyzed Keratin
Hydroxypropyltrimonium Wheat Protein

Benzalkonium Chloride may also serve the same function, but it is also a cationic agent as well as a biocide. Another biocide that may be used is Lysine HCL.

In an exemplary embodiment of such a formulation, an emulsifier may comprise without limitation, at least one of the following:
Cetyl Alcohol (which can also serve as a thickener)
Cetearyl Alcohol
Glyceryl Stearate
Ceteareth-20
PEG-40 Stearate
Dicetyl Phosphate
Ceteth-10 Phosphate

In an exemplary embodiment of such a formulation, the emollient may be Isocetyl Behenate without limitation. The thickener may be Cetyl Alcohol or Stearyl Alcohol without limitation.

In an exemplary embodiment of such a formulation, a preservative may comprise without limitation, at least one of the following:
Phenoxyethanol;
Methylparaben;
Butylparaben;
Ethylparaben;
Propylparaben;
Isobutylparaben.

Examples of typical formulations found to be effective appear in the ten tables that follow. Percentages are given by weight.

TABLE 1

Ingredient	Percent Range	Function
Water	62%-80%	Solvent, Moisturizer
Gluconolactone, Sodium Benzoate	1%	Preservative
Lysine HCL	1%	Conditioner
Polyquaternium - 67	3%-6%	Conditioner
Octoxynol - 9	2%-5%	Surfactant
Polyquaternium - 72	6%-10%	Conditioner
Polyquaternium - 70	0.5%-1%	Conditioner
Dipropylene Glycol Isocetyl Behenate	4%-6%	Emollient
Stearyl Alcohol	1%-3%	Thickener
Cetyl Alcohol	0.25%-1%	Thickener
Ceteareth - 20, PEG - 40 Stearate, Cetearyl Alcohol	1%-2%	Emulsifier
Water, Hydrolyzed Algin	0.5%-1.5%	Conditioner
Hydrolized Soy Protein	0.25%-1%	Conditioner

TABLE 2

Ingredient	Percent Range	Function
Water	72%-88%	Solvent, Moisturizer
Phenoxyethanol Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-6%	Conditioner, Quaternary
Nonoxynol - 10	2%-4%	Surfactant
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate Emulsifier, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Cetearyl Alcohol, Dicetyl Phosphate, Ceteth - 10 Phosphate	0.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.01%-0.05%	Neutralizing Agent

TABLE 3

Ingredient	Percent Range	Function
Water	67%-87%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	3%-7%	Conditioner, Quaternary
Polyquaternium - 72	3%-7%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	1%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-4%	Conditioner, Quaternary
Cetyl Alcohol	1.5%-2.5%	Thickener
Cetearyl Alcohol, Glyceryl PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 4

Ingredient	Percent Range	Function
Water	71%-83%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	4%-6%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternum - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3.5%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.025%-.075%	Neutralizing Agent

TABLE 5

Ingredient	Percent Range	Function
Water	73%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 67	2%-3%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	2%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Cationic, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 6

Ingredient	Percent Range	Function
Water	69%-85%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben,	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	0.25%-0.85%	Conditioner, Quaternary
Polyquaternium - 67	1.5%-3.5%	Conditioner, Quaternary
Polyquaternium - 72	4%-6%	Conditioner, Quaternary
Cetyl Alcohol	1%-3%	Thickener
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	2%-4%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.75%	Neutralizing Agent

TABLE 7

Ingredient	Percent Range	Function
Water	67%-86%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolized Keratin	0.5%-1.5%	Conditioner, Quaternary
Microcare Quat CTC 30	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	3%-5%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 8

Ingredient	Percent Range	Function
Water	58%-74%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	10%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-1.5%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-1.5%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide

TABLE 8-continued

Ingredient	Percent Range	Function
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	.0.05%-0.1%	Neutralizing Agent

TABLE 9

Ingredient	Percent Range	Function
Water	54%-73%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	8%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-4%	Conditioner, Quaternary
Polyquaternium - 67	1%-4%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	2%-3%	Emulsifier
Polybutene	3%-4%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10

Ingredient	Percent Range	Function
Water	52%-71%	Solvent, Moisturizer
Phenoxyethanol, Methylparaben, Propylparaben, Butylparaben, Ethylparaben, Isobutylparaben	1%	Preservative
Lysine HCL	1%	Conditioner, Biocide
Glycerin	9%	Humectant
Glyceryl Acetate/Acrylic Acid Copolymer	1%	Conditioner, Humectant
Polyquaternium - 10	1%-3.5%	Conditioner, Quaternary
Polyquaternium - 67	1%-3%	Conditioner, Quaternary
Polyquaternium - 72	0.5%-2%	Conditioner, Quaternary
Cocodimonium Hydroxypropyl Hydrolyzed Keratin	0.5%-2%	Conditioner, Quaternary
Cetrimonium Chloride	1%-3%	Conditioner, Quaternary
Polyquaternium - 88	1%-3%	Conditioner, Quaternary
Polyquaternium - 22	1%-3%	Conditioner, Quaternary
Cetyl Alcohol	4%	Thickener
Cetearyl Alcohol, Glyceryl Stearate, PEG - 40 Stearate, Ceteareth - 20	1%-4%	Emulsifier
Polybutene	5%-6%	Binder
Benzalkonium Chloride	0.25%-1%	Conditioner, Quaternary, Biocide
Hydroxypropyltrimonium Wheat Protein	1%	Conditioner, Quaternary
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

TABLE 10-continued

Ingredient	Percent Range	Function
Wheat Protein		
Sodium Hydroxide	0.05%-0.1%	Neutralizing Agent

All of the formulations described in TABLE 1-10 representing various embodiments of the Present Invention operate in the manner that was disclosed herein. The same results may be achieved by varying the percentages for the active and inactive ingredients. Varying the percentages for the active ingredients affects the potency of the formulation. Varying the percentages for the inactive ingredients affects the consistency of the formulation. The desired results may be achieved by varying the ingredients and their amounts by those skilled in the art without undue experimentation.

I claim:

1. A method for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein a formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said method comprising:

a) electrostatically attracting the particulate matter to the thin film;

b) holding the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivating the particulate matter by adding at least one ingredient that would render said particulate matter harmless.

2. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising at least one cationic agent and at least one biocidic agent, and wherein said formulation, once applied:

a) electrostatically attracts the particulate matter to the thin film;

b) holds the particulate matter in place by adjusting the adhesion of the thin film to permit said thin film to stick to the skin or tissue and by adjusting the cohesion of the formulation to provide adequate impermeability to the thin film; and,

c) inactivates the particulate matter and renders said particulate matter harmless.

3. The formulation of claim **2** wherein the at least one cationic agent is a polymeric quaternary ammonium compound.

4. The formulation of claim **3** wherein the at least one polymeric quaternary ammonium compound is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

5. The formulation of claim **2** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

6. The formulation of claim **2** wherein the at least one cationic agent is Benzalkonium Chloride.

7. The formulation of claim **2** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

8. A formulation for electrostatically inhibiting harmful particulate matter from infecting an individual through nasal inhalation wherein the formulation is applied to skin or tissue of nasal passages of the individual in a thin film, said formulation comprising:

a) at least one biocidic agent, and

b) at least one quaternary thickener.

9. The formulation of claim **8** wherein the at least one biocidic agent is Benzalkonium Chloride or Lysine HCL.

10. The formulation of claim **8** wherein the at least one quaternary thickener is taken from the group consisting of:

Polyquaternium-10,
Polyquaternium-22,
Polyquaternium-67,
Polyquaternium-70,
Polyquaternium-72, and
Polyquaternium-88.

11. The formulation of claim **8** wherein the at least one cationic agent is Cocodimonium Hydroxypropyl Hydrolyzed Keratin or Hydroxypropyltrimonium Wheat Protein.

12. The formulation of claim **8** wherein the at least one cationic agent is Benzalkonium Chloride.

13. The formulation of claim **8** further comprising:

a) water,

b) a preservative,

c) a conditioner, and

d) an emulsifier.

14. The formulation of claim **13** further comprising a neutralizing agent added to adjust a pH in the range of 5.0 to 6.8.

15. The formulation of claim **13** further comprising a surfactant.

16. The formulation of claim **13** further comprising a thickener.

17. The formulation of claim **13** further comprising an emollient.

18. The formulation of claim **13** further comprising a humectant.

19. The formulation of claim **13** further comprising a binder.

20. The formulation of claim **13** wherein the preservative is taken from the group consisting of:

Phenoxyethanol,
Methylparaben,
Butylparaben,
Ethylparaben, and
Isobutylparaben.

21. The formulation of claim **13** wherein the emulsifier is taken from the group consisting of:

Cetyl Alcohol,
Cetearyl Alcohol,
Glyceryl Stearate,
Ceteareth-20,
PEG-40 Stearate,
Dicetyl Phosphate,
Ceteth-10 Phosphate.

22. The formulation of claim **16** wherein the thickener is Cetyl Alcohol or Stearyl Alcohol.

23. The formulation of claim **13** wherein:

a) the amount of water ranges from 54% to 90% by weight

b) the amount of the quaternary thickener ranges from 0.5% to 5.0% by weight,

c) the amount of biocidic agent ranges from 0.25% to 2% by weight,

d) the amount of emulsifier ranges from 0.5% to 4% by weight.

* * * * *

EXHIBIT C

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
12/467,271	05/16/2009	Ashok Wahi	51900-TRUTEK-009	7676

34325 7590 08/25/2011

STANLEY H. KREMEN
4 LENAPE LANE
EAST BRUNSWICK, NJ 08816

EXAMINER	
HENLEY III, RAYMOND J	

ART UNIT	PAPER NUMBER
1629	

NOTIFICATION DATE	DELIVERY MODE
08/25/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

uspto@patentsgroup.com

Office Action Summary	Application No.	Applicant(s)	
	12/467,271	WAHI, ASHOK	
	Examiner	Art Unit	
	RAYMOND HENLEY III	1629	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *5/16/2009 and papers subsequent thereto*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ An election was made by the applicant in response to a restriction requirement set forth during the interview on _____; the restriction requirement and election have been incorporated into this action.

4)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

5)☒ Claim(s) *1-23* is/are pending in the application.

5a) Of the above claim(s) _____ is/are withdrawn from consideration.

6)☐ Claim(s) _____ is/are allowed.

7)☒ Claim(s) *1-23* is/are rejected.

8)☐ Claim(s) _____ is/are objected to.

9)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

10)☐ The specification is objected to by the Examiner.

11)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

12)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/16/2009*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

CLAIMS 1-23 ARE PRESENTED FOR EXAMINATION

Applicant's Information Disclosure Statement filed May 16, 2009 has been received and entered into the application. As reflected by the attached, completed copies of form PTO/SB/08, (3 sheets), the cited references have been considered.

Overcoming the Rejection Below

In order to overcome the rejection set forth *infra*, it is suggested that Applicant consider amending claims 1, 2 and 8 so as to delete the term "preventing" and replacing it with the term "inhibiting". While the latter is not specifically set forth in the present specification, it is nevertheless deemed that the concept thereof clearly finds support therein when the specification's teachings are taken as a whole, i.e., no new matter would be introduced by the introduction of the term "inhibition" in the claims.

Claim Rejection - 35 USC § 112, First Paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for, at the most, inhibition of infections, does not reasonably provide enablement for the prevention of the same, (see claims 1, 2 and 8; and thus the claims dependent therefrom). The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Burden on the Examiner for Making a Rejection Under 35 U.S.C. § 112 First Paragraph

As set forth in *In re Marzocchi*, 169 USPQ 367, 370 (CCPA 1971):

"[A] [s]pecification disclosure which contains teaching of manner and process of making and using the invention in terms corresponding to the scope to those used in describing and defining subject matter sought to be patented must be taken as in compliance with enabling requirement of first paragraph of 35 U.S.C. 112 *unless there is reason to doubt the objective truth of statements contain therein which must be relied on for enabling support*; assuming that sufficient reason for such doubt exists, a rejection for failure to teach how to make and/or use will be proper on that basis, such a rejection can be overcome by suitable proofs indicating that teaching contained in specification is truly enabling." (emphasis added).

Here, the objective truth of the statement that an infection, which is taken to mean the introduction of an infectious element through the outside of a given host and into the system of such host, (see MPEP § 2113; terms given their broadest reasonable interpretation), may be prevented, (which again, given its broadest, reasonable interpretation), i.e., a material is ever kept from introduction into the system of a host, is doubted because the present claims merely recite a pharmacological composition while an effective prevention against the introduction of an infectious material into a host, especially where such material does not cause any pathology, would require that the exterior system of the host to be completely blocked so as to preclude any infectious material passing through such system and arriving within the system of the host.

In reading the present specification as a whole, it appears the tenor thereof is that infections, whether they cause a pathology or not, may be **inhibited** rather than be prevented. The former allowing at least one infectious material to pass into the system of the host rather than the latter which indicates that not even one of the infectious material is allowed to infect, i.e., pass into the system of the host.

As indicated above, the term "preventing" is here being interpreted as being synonymous with a circumstance such as where a vaccine is administered against a pathogen and the host to whom such was administered does not suffer from the pathogen's effect even when present in the host's system. As such the term "preventing" circumscribes a circumstance of almost absolute success. Because such success is not reasonably possible with the treatment of most infectious diseases/disorders, especially those having an etiology and pathophysiological manifestations as complex/poorly understood as encompassed by the present claims, the specification, which lacks an objective showing where prevention is actually manifest, is viewed as lacking an enabling disclosure of the same.

The Examiner notes that the term "prevent" is not *necessarily* synonymous with "cure" or the action of a vaccine, but such interpretation is proper given that "During patent examination, the pending claims must be 'given their broadest reasonable interpretation consistent with the specification.' *In re Hyatt*, 211 F.3d 1367, 1372, 54 USPQ2d 1664, 1667 (Fed. Cir. 2000). Applicant always has the opportunity to amend the claims during prosecution, and broad interpretation by the examiner reduces the possibility that the claim, once issued, will be interpreted more broadly than is justified. *In re Prater*, 415 F.2d 1393, 1404-05, 162 USPQ 541, 550-51 (CCPA 1969)." (MPEP § 2111).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to RAYMOND HENLEY III whose telephone number is (571)272-0575. The examiner can normally be reached on M-F, 8:30 am to 4:00 pm Eastern Time.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey S. Lundgren can be reached on 571-272-5541. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Raymond J Henley III/
Primary Examiner
Art Unit 1629

August 19, 2011